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09/729,034	12/04/2000	Cheryl A. Pederson	56094US002	4710

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EXAMINER	
PAULS, JOHN A	

ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
08/29/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	09/729,034	PEDERSON ET AL.	
	Examiner	Art Unit	
	JOHN PAULS	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Claims filed and 3 June, 2009 and BPAI*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the Administrative Remand ordered by the Board of Patent Appeals and Interferences on 27 July, 2012. The BPAI and the group Director of Technology Center 3600 determined that the Applicant/Appellant has not had an adequate opportunity to respond to the new grounds of rejection presented in the Examiner's Answer mailed on 10 June, 2010. This Office Action present that opportunity and repeats the rejection found in the 10 June, 2010 Examiner's Answer.

2. Claims 12 - 49 are currently pending and have been examined. This rejection is based on the Claims filed on 3 June, 2009.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12-21 and 37-49 contain a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not seem to delineate a "means for identifying"; "means for generating" nor a "means for constructing".

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 12-22 and 26-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram et al., 'Guideline for prevention of surgical site infection" (hereinafter Guidelines) in view of Ormond-Walshe, Sarah, "Computerized databases in infection control" (hereinafter Walshe) and in further view of US Patent Number 6,157,853 to Blume and in even further view of US Patent Number 5,562,448 to Mushabac and in even further view of US Patent Application Publication 2002/0077865 to Sullivan and in even further view of US Patent Number 6,509,730 to Afsah.

CLAIMS 12 and 13

Guidelines discloses a method for managing the occurrence or risk of surgical site infection incident to a surgical procedure (Guidelines: pages 100-120), the method comprising:

- *means for identifying a plurality of stages (mapping) of operative care associated with the surgical procedure, including at least a preoperative stage, an intra-operative stage, and a postoperative stage;* (Guidelines: page 98)*;*
- *means for identifying one or more points-of-care within each identified stage of operative care associated with the surgical procedure;* (Guidelines: page 98)*;*
- *for each point-of-care associated with the surgical procedure, means for identifying one or a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection (Guidelines: page 98);*
- *for identified surgical site infection risks, identifying at least one practice for either or both managing or reducing the risks, either individually for each risk or collectively for more than one risk;* (Guidelines: pages 106-116)*.*

- *means for identifying one or more compliance indicators associated with the surgical procedure within each point-of-care to provide a set of sequential practices throughout each of the stages of operative care;* (Guidelines: pages 100-120).

Guidelines does not explicitly disclose

- *aligning the practices in a manner that provides a desired management of the overall occurrence or risk of surgical site infection.*

However, Walshe discloses aligning the practices in a manner that provides a desired management (monitoring) of the overall occurrence or risk of surgical site infection (i.e. establishment of surveillance and control programs was strongly associated with reductions)(page 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of reducing infection rates (page 3).

Guidelines and Walshe does not explicitly disclose that *for each of the compliance indicators, means for generating a flag when a given health care practice is not in compliance with a rule to align the health care practices to the rule*, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care

practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2), since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2), since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

The above mentioned references do not teach the following feature which is taught by Sullivan (Section [0055]):

- *wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk or surgical site infection are selectable for a given health care facility.*

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Sullivan with the motivation of having a means of allowing a physician to have immediate recall of difficult to remember historical items, as recited in Sullivan (Section [0055]), since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

The above mentioned references do not teach the following feature which is taught by Afsah (Col. 6, Ln. 9-20):

- *wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.*

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Afsah with the motivation of having a means of determining a benchmark value, as recited in Afsah (Col. 6, Ln. 9-11), since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIMS 14 - 21

Claims 14 – 21 are substantially similar in scope to claims 12-13 and are rejected on the same basis. The limitations claimed in these claims are taught in Guidelines (Pages 100-120).

CLAIMS 22 and 36

Guidelines discloses a method for managing risks for surgical site infections incident to a surgical procedure, the method comprising:

- *evaluating a practice associated with the surgical procedure that poses an infection risk during a stage or the surgical procedure* (Guidelines: Page 106-116);

Guidelines does not disclose *storing data indicative of the practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedures*, however, this feature is taught by Walshe (Walshe: Page 3, Paragraph 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of developing an enhanced means of reducing infection rates (page 3), since so doing could be performed readily

and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Guidelines in view of Walshe does not teach a step of *identifying via a compliance indicator when the data indicative of the practice associated with a procedure is not in compliance with a rule established for the practice*, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule and also does not teach generating a report that represents a compilation of measurement data associated with the surgical procedure, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2), since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2), since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Sullivan with the motivation of having a means of allowing a physician to have immediate recall of difficult to remember historical items, as recited in Sullivan (Section [0055]), since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

The above mentioned references do not teach the following feature which is taught by Afsah (Col. 6, Ln. 9-20):

wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Afsah with the motivation of having a means of determining a benchmark value, as recited in Afsah (Col. 6, Ln. 9-11), since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIMS 26 - 33 and 37 - 49

Claims 26-33 and 37-49 repeat features previously addressed in the rejection of claims 12-25 and are rejected on the same basis.

CLAIMS 34 and 35

The combined teachings of Mangram in view of Walshe in view of Blume in view of Mushabac in view of Sullivan and in even further view of Afsah teach that the compliance indicator defines a value within a pre-defined quality scale and that the quality scale ranges from 1 to 10

(Mushabac: Col. 4, Ln. 65-Col. 5, Ln. 2). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the Guidelines reference with these teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in (Mushabac: Col. 4, Ln. 65-Col. 5, Ln. 2) since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

5. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe in view of Blume in view of Mushabac in view of Sullivan in view of Afsah, as applied to claim 22, above, and in even further view of US Patent Number 6,662,081 to Jacober.

CLAIM 23

The Guidelines reference does not teach the following feature which is taught by the Jacober reference:

the step of identifying when the data indicative of the practice is not in compliance with the rule comprises generating a flag for the data (Jacober: Claims 32 and 35).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the Guidelines references with the above mentioned teachings from Jacober with the motivation for having a means of producing an alert when data is not in compliance with a rule, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIMS 24 and 25

The Guidelines reference does not teach the following feature which is taught by the Jacober reference:

a step of prompting medical personnel to take further action when the flag is generated (Jacober: Claims 32-35) and *the flag is cleared when the further action is taken* (Jacober: Claim 34). (Note: In Jacober the medical personnel take further action by sliding the tray of the medication dispenser to remove the medication (Claim 32)).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the Guidelines references with the above mentioned teachings from Jacober with the motivation for having a means of producing an alert when data is not in compliance with a rule, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Response to Arguments

(1) In response to applicant's argument that that Mushabac and Blume references are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both the instant application and the Mushabac and the Blume references deal with the problem of generating either flags or alerts when a surgical procedure is not in compliance with a rule established for practice, and as has been set forth above, in the rejection of these claims, proper motivation exists for combining these teachings with those of the Guidelines reference. In

addition, the Office would like to point out that adding the well known elements from the Mushabac and Blume references to the Guidelines reference does not produce any new or unexpected result.

(2) Applicants argue that the cited portions of the Sullivan reference are not supported by its provisional application. However, the teachings of the Sullivan patent application publication which are recited in Figure 23 and Section [0055] of the patent application publication are recited on page 19 of its supporting provisional patent application (60/245,255) on page 19, from lines 13-20. Moreover, the Sullivan reference along with the other prior art references used in the rejection of these claims teach surgical procedures and it is inherent that almost all surgeries involve either the cutting of human tissue or the step of making incisions or openings in human bodies and therefore the risk of surgical site infections from the list of surgeries taught in the prior art is inherent in both Sullivan and the other prior art references used in the rejections of these claims.

(3) Applicants argue that the Afsah reference does not teach "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery services." However, the Office would like to point out that this feature is taught in Figure 16 of the provisional patent application of the Afsah reference (US Provisional Patent Application Number 60/185,129) . Figure 16 of this application clearly shows that the compliance indicators which measure a quality of the delivery of health care delivery services are quantified.

(4) Applicants argue that the Jacober reference does not teach or suggest the identification of when data indicative of the practice associated with the surgical procedure is not

in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure. However, Jacober teaches this feature (Jacober: Claims 32-35).

CONCLUSION

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **(571) 270-5557.** The Examiner can normally be reached on Monday to Friday 7:30 to 5:00. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see *http://portal.uspto.gov/external/portal/pair*. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197**.

Official replies to this Office action may now be submitted electronically by registered users of the EFS-Web system. Information on EFS-Web tools is available on the Internet at: *http://www.uspto.gov/patents/process/file/efs/guidance/index.jsp*. An EFS-Web Quick-Start Guide is available at: *http://www.uspto.gov/ebc/portal/efs/quick-start.pdf*.

Alternatively, official replies to this Office action may still be submitted by any ***one*** of fax, mail, or hand delivery. **Faxed replies should be directed to the central fax at (571) 273-8300**. Mailed replies should be addressed to "Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450." Hand delivered replies should be delivered to the "Customer Service Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314."

/JOHN A. PAULS/
Examiner, Art Unit 3686
Date: 24 August, 2012